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(54) **SYSTEMS AND METHODS FOR ANCHORING AND SEALING A PROSTHETIC HEART VALVE**

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See application file for complete search history.

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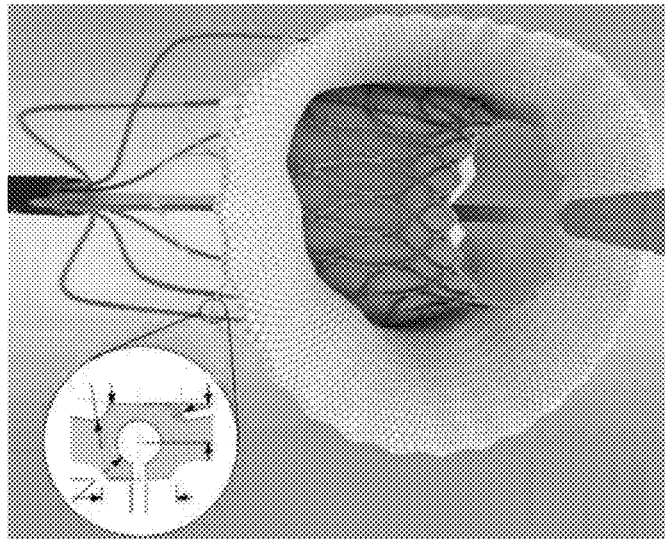
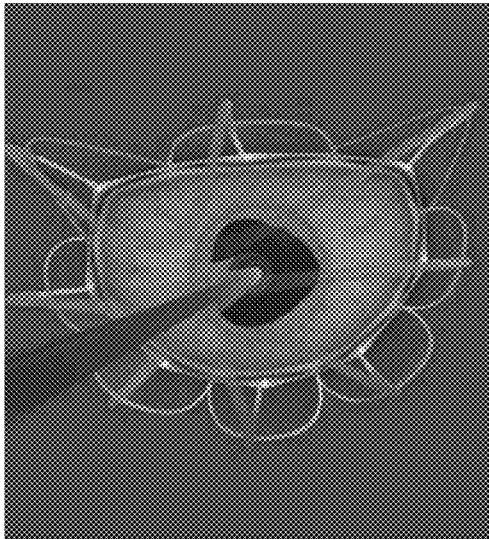
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(57) **ABSTRACT**

A method of implanting a prosthetic heart valve includes advancing a prosthetic heart valve to an implantation location within a patient's body, positioning the prosthetic heart valve within a native heart valve annulus, expanding a frame of the prosthetic heart valve from a first contracted configuration to a first expanded configuration, and then contracting the frame to a second contracted configuration. The prosthetic heart valve may be repositioned and then re-expanded from the second contracted configuration to a second expanded configuration. The prosthetic heart valve is preferably released from the delivery apparatus while in the second expanded configuration. Releasing the prosthetic heart valve from the delivery apparatus may result in radial expansion of a flange portion of the prosthetic heart valve.

10 Claims, 13 Drawing Sheets



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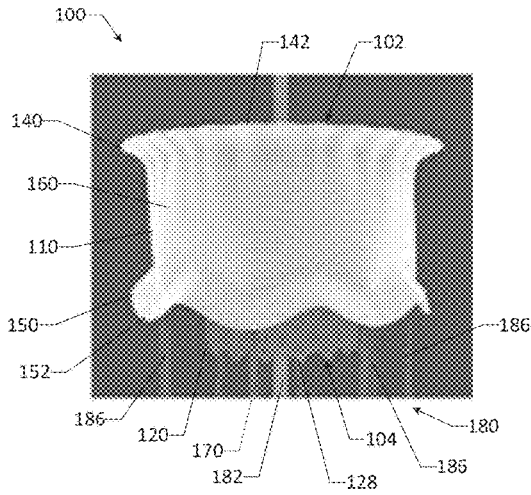


FIG. 1A

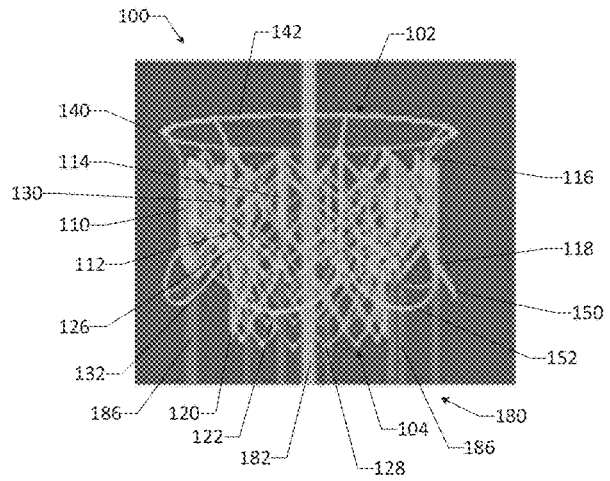


FIG. 1B

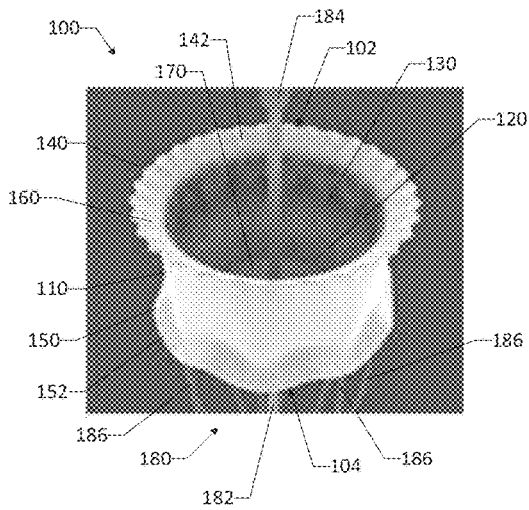


FIG. 1C

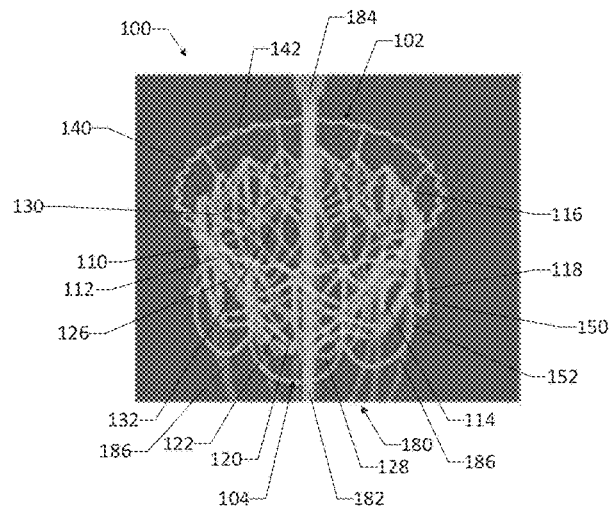


FIG. 1D

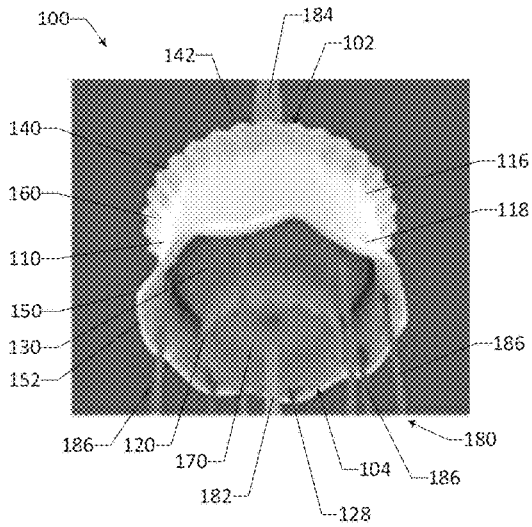


FIG. 1E

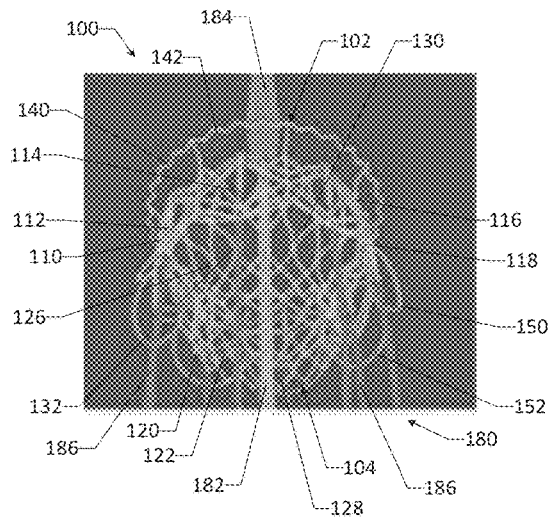


FIG. 1F

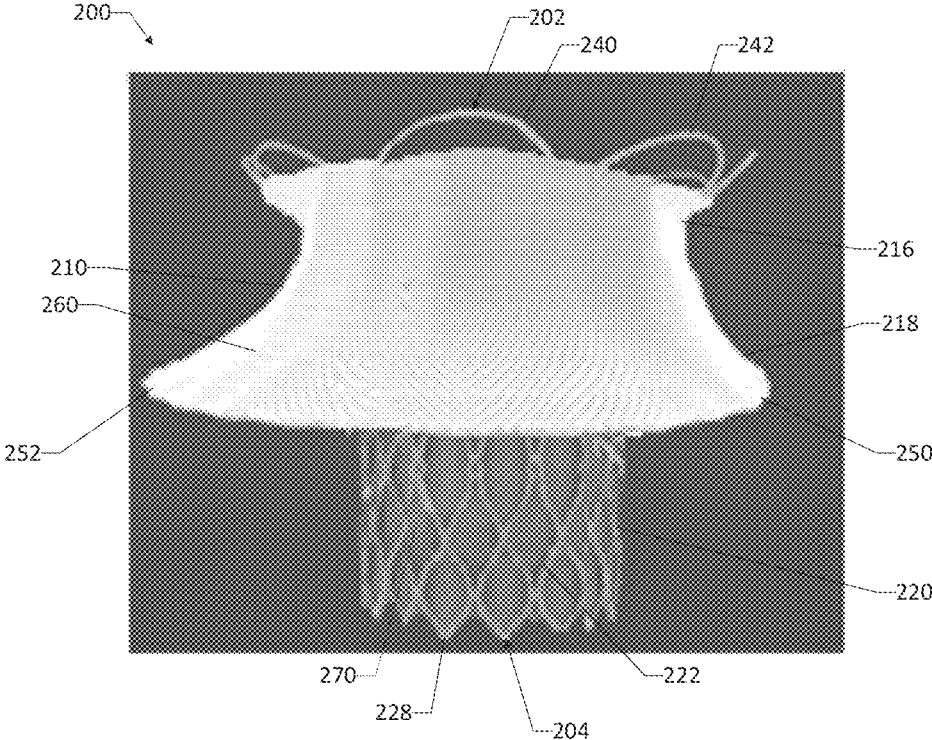


FIG. 2A

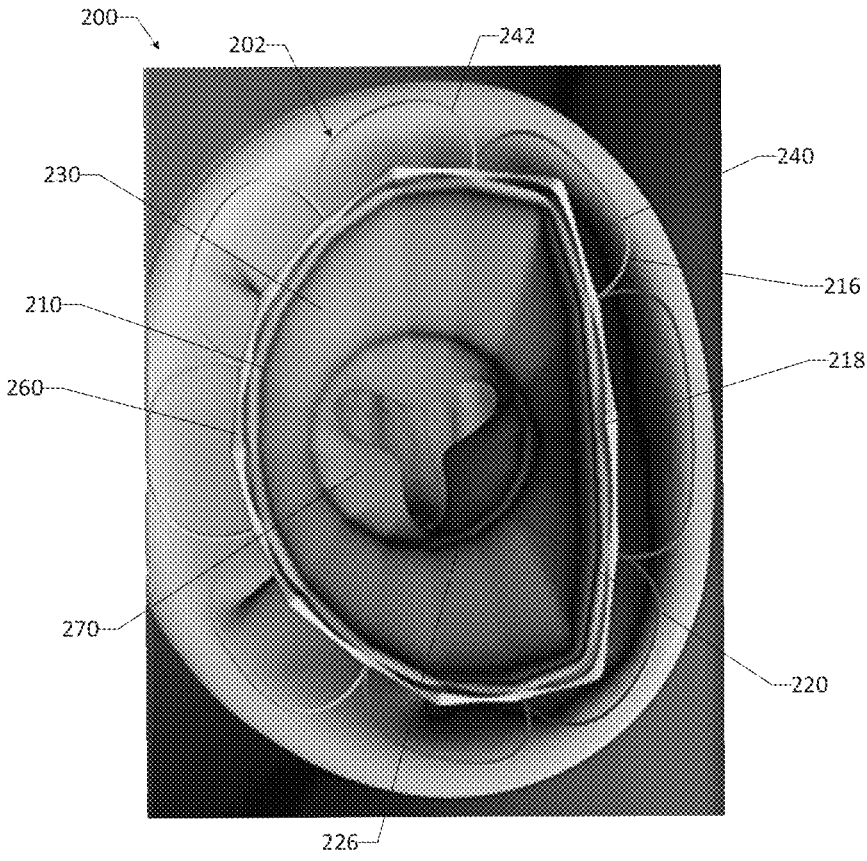


FIG. 2B

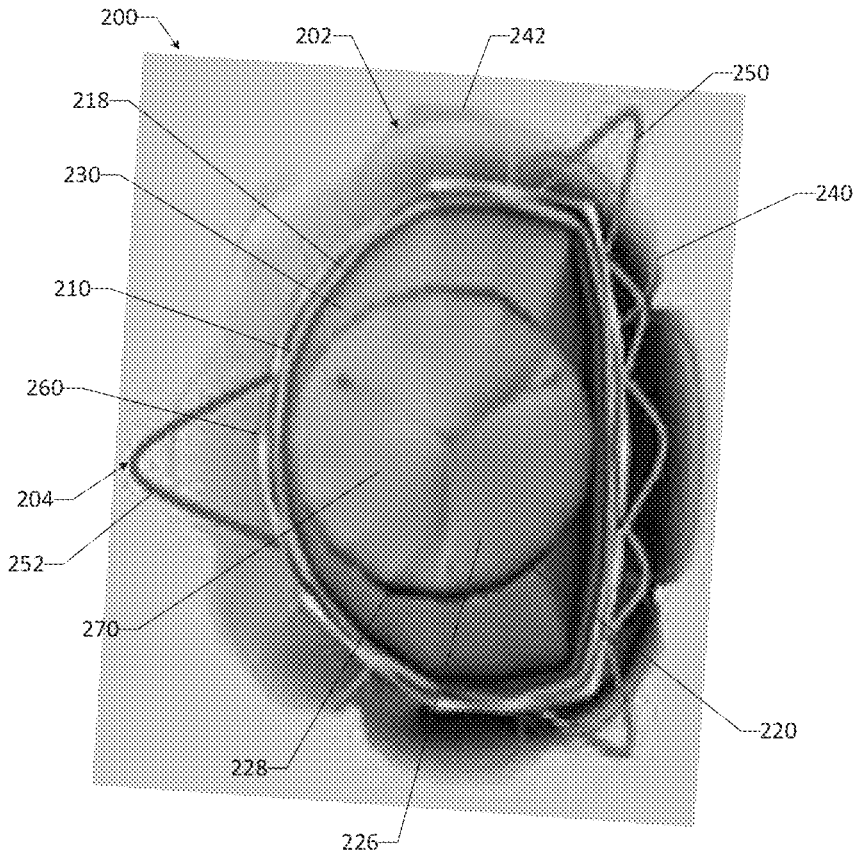


FIG. 2C

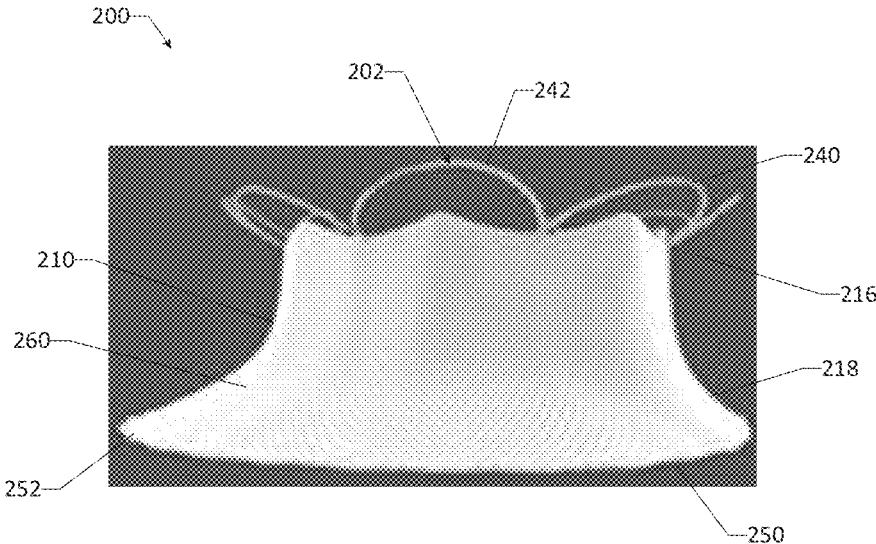


FIG. 2D

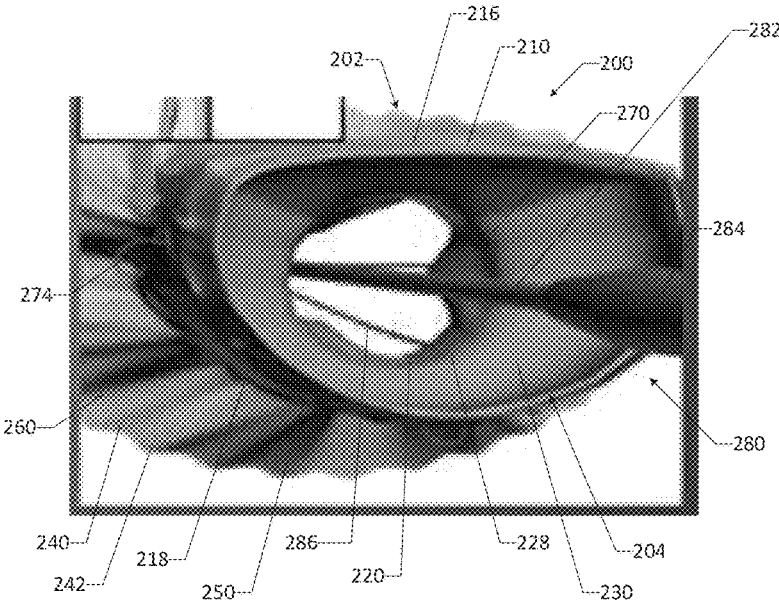


FIG. 2E

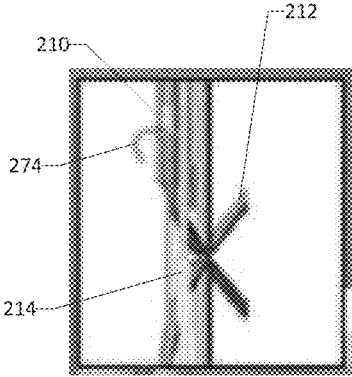


FIG. 2F

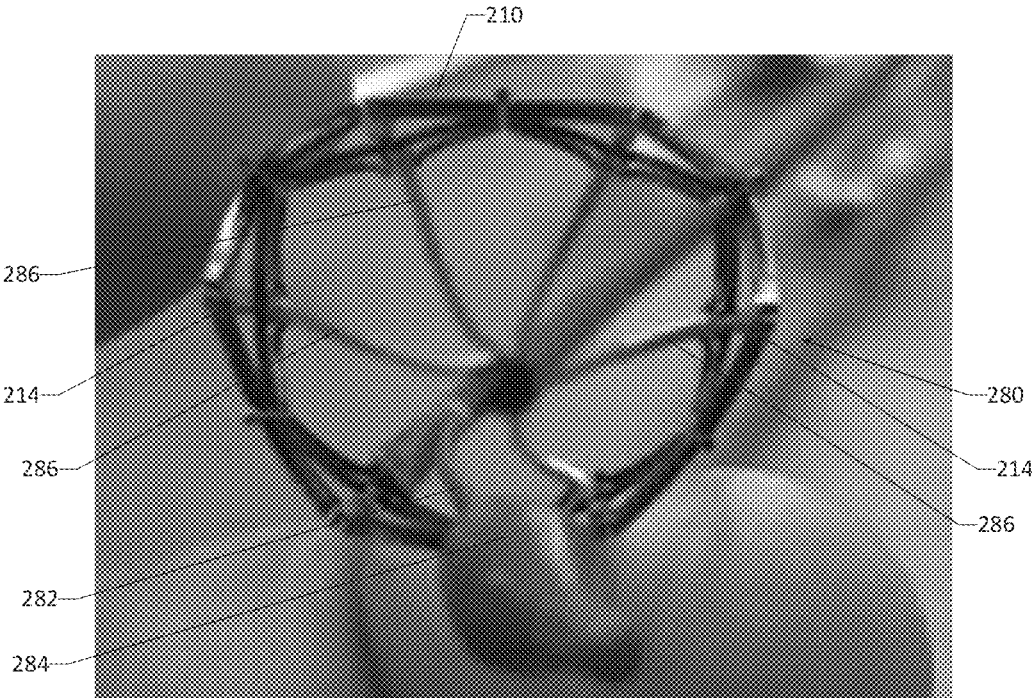


FIG. 2G

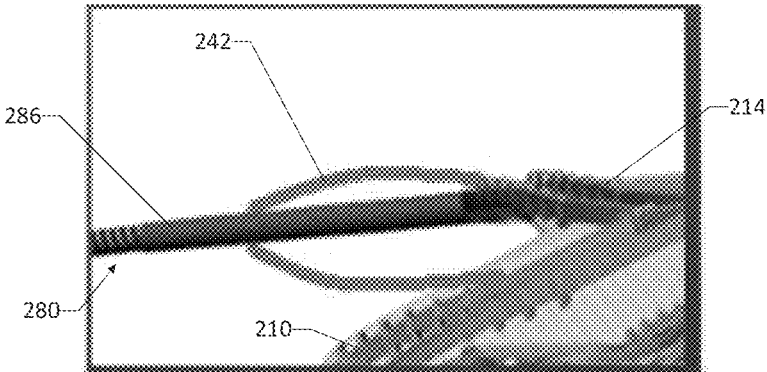


FIG. 2H

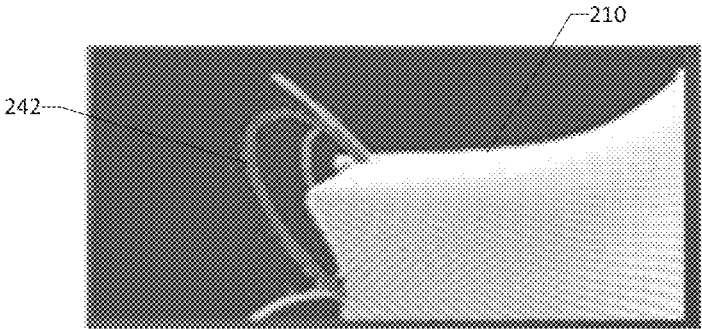


FIG. 2I

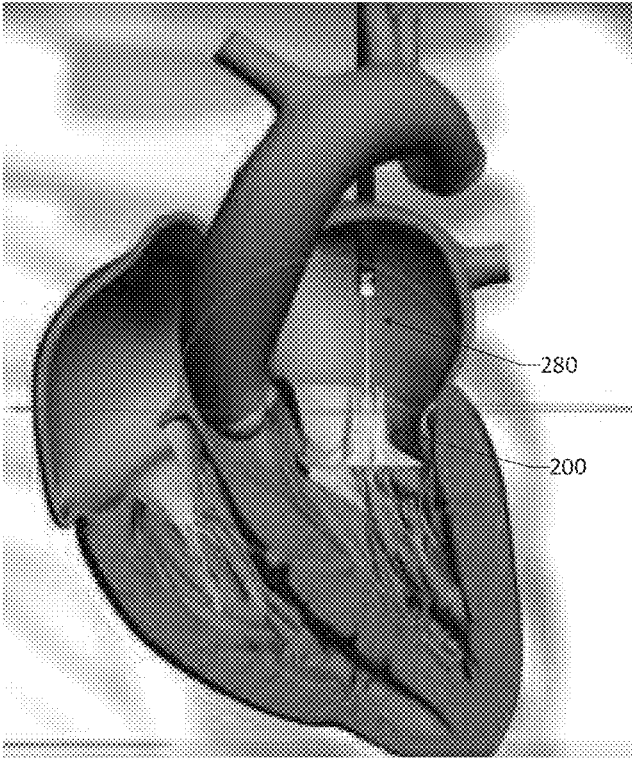


FIG. 2J

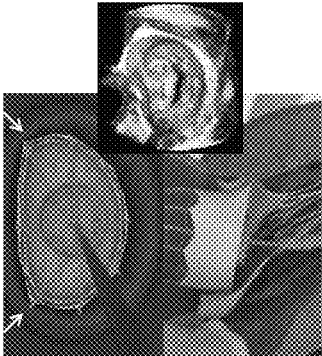


FIG. 3C

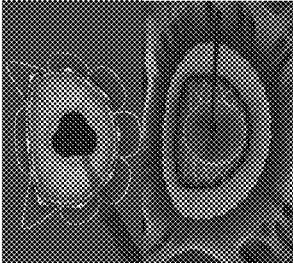


FIG. 3F



FIG. 3B

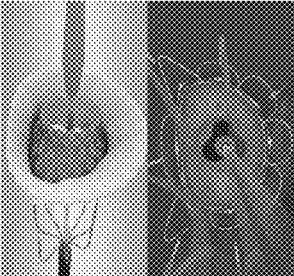


FIG. 3E

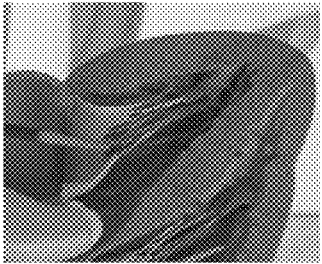


FIG. 3A

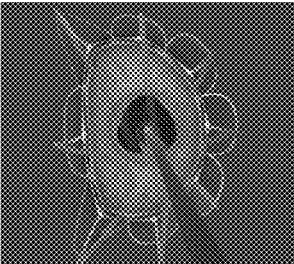


FIG. 3D

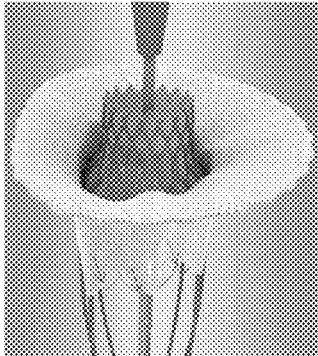


FIG. 3I

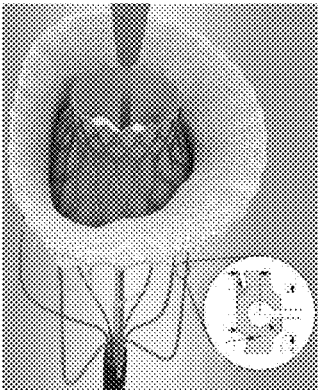


FIG. 3H

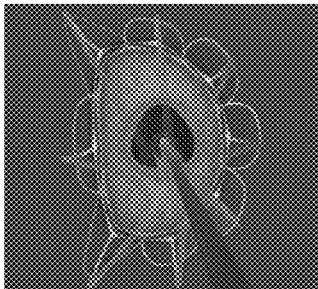


FIG. 3G

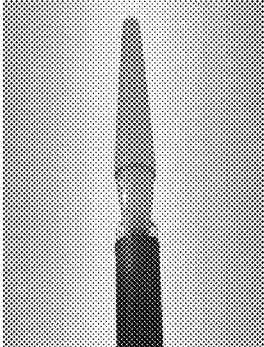


FIG. 3L

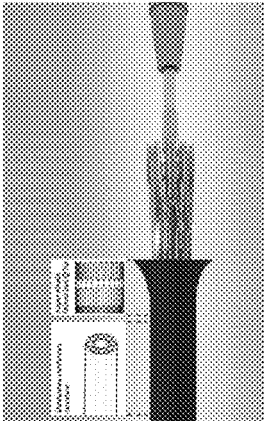


FIG. 3K

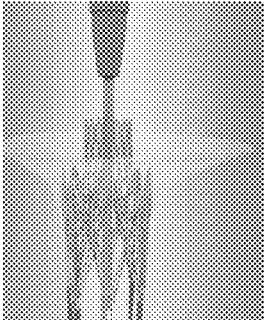


FIG. 3J

SYSTEMS AND METHODS FOR ANCHORING AND SEALING A PROSTHETIC HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 15/191,054, filed Jun. 23, 2016, which claims the benefit of U.S. Provisional Application No. 62/183,562, filed Jun. 23, 2015. Each related application is incorporated by reference herein.

FIELD OF THE DISCLOSURE

The present disclosure relates generally to prosthetic heart valves and methods for replacing diseased or defective native heart valves, and more particularly to an expandable prosthetic heart valve including features for anchoring and sealing the prosthetic heart valve onto a native human heart and related methods for implanting the prosthetic heart valve to replace a diseased or defective native heart valve.

BACKGROUND OF THE DISCLOSURE

Various types of prosthetic heart valves are commonly used in valve replacement surgery to replace a diseased or defective native heart valve, such as an aortic valve, a mitral valve, a pulmonary valve, or a tricuspid valve, of a native human heart. A prosthetic heart valve generally may include a frame or other support structure configured for positioning at an implantation site at or near the native heart valve and anchoring onto the native heart, and an occluder member, such as a multi-leaflet valve, attached to the frame and configured for controlling blood flow through the prosthetic heart valve. Upon implantation of the prosthetic heart valve, the frame may maintain the relative position of the prosthetic heart valve within the native heart, and the occluder member may control blood flow in a manner similar to the native heart valve, thereby restoring desired function of the heart.

According to traditional procedures, heart valve replacement may be performed via open heart surgery, which may require cardiopulmonary bypass and may present a significant risk of certain complications. In recent years, less-invasive procedures for heart valve replacement have been developed, which may eliminate the need for cardiopulmonary bypass and may decrease the risk of complications as compared to open heart surgery. For example, certain prosthetic heart valves may be implanted via a transapical approach, a transatrial approach, a transfemoral approach, a transseptal approach, a subclavian approach, a direct aortic puncture approach, or other vascular access approaches. Each type of approach for implanting prosthetic heart valves may present certain benefits and drawbacks. For example, the transapical approach may provide a direct, “straight shot” approach for replacing certain native heart valves, may allow a physician to leverage past experience in performing transcatheter aortic valve replacement (TAVR) procedures, and may allow a physician to have high degree of control over the prosthetic heart valve and instruments used to implant the heart valve. However, the transapical approach may be challenging in certain patients due to poor tissue quality at the apex of the heart and/or a relatively large outer diameter of the prosthetic heart valve being implanted, may

result in left ventricle dysfunction, may present issues of sub-valvular entanglement, and may be more invasive than other potential approaches.

The transatrial approach may provide a direct antegrade approach for replacing certain native heart valves, may avoid sub-valvular anatomy, may eliminate the need to puncture the left ventricle, and may be less sensitive to the size of the outer diameter of the prosthetic heart valve being implanted. However, the transatrial approach may present challenges in steering and navigating the prosthetic heart valve through the anatomy to the desired implantation site, may present a steep learning curve for a physician having experience only with the transapical approach, and may be more invasive than other potential approaches. The transseptal approach may provide a direct antegrade approach for replacing certain native heart valves, may eliminate the need to puncture the left ventricle, and may allow a physician to leverage past experience in performing other procedures through a transseptal puncture. However, the transseptal approach may present challenges in steering and navigating the prosthetic heart valve through the anatomy to the desired implantation site, may require a physician to deliver the prosthetic heart valve over a relatively long distance as compared to other potential approaches, may present challenges in patients having an atrial and/or septal defect, in particular when the prosthetic heart valve has a relatively large outer diameter, and may require venous or arterial access in order to deliver the prosthetic heart valve to the desired implantation site.

Currently, less-invasive approaches are most commonly used in performing aortic valve replacement procedures, although it would be desirable to use less-invasive approaches in replacing mitral valves, pulmonary valves, and/or tricuspid valves in a similar manner. In view of the differences between the aortic valve and the other native heart valves, however, prosthetic heart valves and related instruments configured for aortic valve replacement generally would not be suitable for replacing the other native heart valves. Accordingly, there remains a need for a prosthetic heart valve that is suitable for replacement of the mitral valve, the pulmonary valve, and/or the tricuspid valve. It will be appreciated that a prosthetic heart valve configured for mitral, pulmonary, and/or tricuspid valve replacement may require certain differences in design and function, as compared to prosthetic heart valves configured for aortic valve replacement, in order to be implanted via a less-invasive approach and to function in a suitable manner. In particular, such a prosthetic heart valve should accommodate or conform to the shape and structure of the native heart valve and/or surrounding anatomy without compromising the integrity or function of the surrounding anatomy or the occluder member of the prosthetic heart valve. Such a prosthetic heart valve also should securely anchor onto the native heart tissue to prevent or inhibit migration of the prosthetic heart valve from the implantation site. Further, such a prosthetic heart valve should form a seal against the native heart tissue to prevent or inhibit paravalvular leakage.

SUMMARY OF THE DISCLOSURE

Various embodiments described herein provide prosthetic heart valves and related methods for implanting a prosthetic heart valve to replace a diseased or defective native heart valve. According to one aspect, a prosthetic heart valve for replacing a diseased or defective native heart valve is provided. In one embodiment, the prosthetic heart valve may include an outer frame, an inner frame positioned at least

partially within the outer frame, and an occluder member positioned at least partially within the inner frame. The prosthetic heart valve also may include an atrial flange extending from an atrial end of the outer frame, and a ventricular flange extending from a ventricular end of the outer frame, wherein at least a portion of the atrial flange extends radially outward beyond the ventricular flange.

In another embodiment, the prosthetic heart valve may include an outer frame having a D-shaped cross-sectional shape in a plane orthogonal to a longitudinal axis of the prosthetic heart valve, and an inner frame positioned at least partially within the outer frame and having a circular cross-sectional shape in the plane orthogonal to the longitudinal axis of the prosthetic heart valve. The prosthetic heart valve also may include an occluder member positioned at least partially within the inner frame, an atrial flange extending from an atrial end of the outer frame, and a ventricular flange extending from a ventricular end of the outer frame.

In still another embodiment, the prosthetic heart valve may include an expandable outer frame having a D-shaped cross-sectional shape in a plane orthogonal to a longitudinal axis of the prosthetic heart valve, and an expandable inner frame positioned at least partially within the outer frame and having a circular cross-sectional shape in the plane orthogonal to the longitudinal axis of the prosthetic heart valve. The prosthetic heart valve also may include an occluder member positioned at least partially within the inner frame, an atrial flange extending from an atrial end of the outer frame, and a ventricular flange extending from a ventricular end of the outer frame, wherein at least a portion of the atrial flange extends radially outward beyond the ventricular flange.

These and other aspects and embodiments of the present disclosure will be apparent or will become apparent to one of ordinary skill in the art upon review of the following detailed description when taken in conjunction with the several drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In describing the various embodiments of the present disclosure, reference is made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

FIG. 1A is a side view of a prosthetic heart valve and a portion of a delivery device in accordance with one or more embodiments of the present disclosure, showing the prosthetic heart valve in an expanded state.

FIG. 1B is a side view of an outer frame, an inner frame, an atrial flange/skirt, and a ventricular flange/skirt of the prosthetic heart valve and a portion of the delivery device of FIG. 1A, showing the prosthetic heart valve in the expanded state.

FIG. 1C is a top perspective view of the prosthetic heart valve and a portion of the delivery device of FIG. 1A, showing the prosthetic heart valve in the expanded state.

FIG. 1D is a top perspective view of the outer frame, the inner frame, the atrial flange/skirt, and the ventricular flange/skirt of the prosthetic heart valve and a portion of the delivery device of FIG. 1A, showing the prosthetic heart valve in the expanded state.

FIG. 1E is a bottom perspective view of the prosthetic heart valve and a portion of the delivery device of FIG. 1A, showing the prosthetic heart valve in the expanded state.

FIG. 1F is a bottom perspective view of the outer frame, the inner frame, the atrial flange/skirt, and the ventricular flange/skirt of the prosthetic heart valve and a portion of the delivery device of FIG. 1A, showing the prosthetic heart valve in the expanded state.

FIG. 2A is a side view of a prosthetic heart valve in accordance with one or more embodiments of the present disclosure, showing the prosthetic heart valve in an expanded state.

FIG. 2B is a top view of the prosthetic heart valve of FIG. 2A, showing the prosthetic heart valve in the expanded state.

FIG. 2C is a bottom view of the prosthetic heart valve of FIG. 2A, showing the prosthetic heart valve in the expanded state.

FIG. 2D is a side view of an outer frame, an atrial flange/skirt, and a ventricular flange/skirt of the prosthetic heart valve of FIG. 2A, showing the outer frame, the atrial flange/skirt, and the ventricular flange/skirt in the expanded state.

FIG. 2E is a perspective view of a portion of the prosthetic heart valve of FIG. 2A and a portion of a delivery device attached to the prosthetic heart valve, showing the prosthetic heart valve in the expanded state and an anchor of the prosthetic heart valve in a deployed state.

FIG. 2F is a detailed side view of a portion of the prosthetic heart valve of FIG. 2A, showing the anchor of the prosthetic heart valve in the deployed state.

FIG. 2G is a bottom perspective view of the outer frame of the prosthetic heart valve of FIG. 2A and a portion of the delivery device, showing the outer frame in the expanded state.

FIG. 2H is a detailed side view of a portion of the prosthetic heart valve of FIG. 2A and a portion of the delivery device, showing a petal of the atrial flange/skirt of the prosthetic heart valve in a collapsed state.

FIG. 2I is a detailed side view of a portion of the prosthetic heart valve of FIG. 2A, showing petals of the atrial flange/skirt in an expanded state.

FIG. 2J is a partial cross-sectional side view of the prosthetic heart valve of FIG. 2A positioned within a native mitral valve of a native human heart, showing the outer frame and the atrial flange/skirt of the prosthetic heart valve in a collapsed state and the ventricular flange/skirt in an expanded state.

FIG. 3A is a side view of a sheathed prosthetic heart valve, beginning a series in FIGS. 3A-3F showing a computer-assisted mitral valve replacement of the invention.

FIG. 3B is a side view of the prosthetic heart valve of FIG. 3A showing unsheathing of the ventricular skirt.

FIG. 3C is a composite top view, a side view and a computer generated positioning top view of the prosthetic heart valve of FIG. 3A showing controlled expansion of the frame, allowing repositioning or re-sheathing by contracting the frame.

FIG. 3D is a top view of the prosthetic heart valve of FIG. 3A showing the atrial petals open for positioning and hemodynamic function verification.

FIG. 3E is a composite of a top perspective view and a top view of the prosthetic heart valve of FIG. 3A showing release of the control wires in the final position.

FIG. 3F is a composite top view and a bottom view of the prosthetic heart valve of FIG. 3A showing removing the guide wire and final verification of the valve position and function.

FIG. 3G is a top view of a prosthetic heart valve, beginning a series in FIGS. 3G-3L, showing how a single articulating operation minimizes complexity in re-sheathing atrial petals after deployment.

FIG. 3H is a bottom perspective view of the prosthetic heart valve of FIG. 3G showing how control wires pass outside or within slots in atrial petals to enable inward deflection.

5

FIG. 3I is a bottom perspective view of the prosthetic heart valve of FIG. 3G showing coordinated contraction of stent and forward motion of sheath to allow for petals to be retracted into the frame.

FIG. 3J is a side view of the prosthetic heart valve of FIG. 3G showing contraction and re-sheathing.

FIG. 3K is a side view of the prosthetic heart valve of FIG. 3G showing that the structure from a multi-lumen tube allows the use of wires to pull petals inward without damaging the tip.

FIG. 3L is a side view of the prosthetic heart valve of FIG. 3G showing the tip recoiling into a straight configuration after passing over the implant.

DETAILED DESCRIPTION OF THE DISCLOSURE

Various embodiments of the present disclosure provide improved expandable prosthetic heart valves, delivery devices, and methods for replacing diseased or defective native heart valves. Such expandable prosthetic heart valves, delivery devices, and methods may address one or more of the above-described drawbacks of existing technology for heart valve replacement. As described below, the expandable prosthetic heart valves, delivery devices, and methods provided herein may be configured for mitral valve replacement, although the expandable prosthetic heart valves, delivery devices and methods alternatively may be configured for aortic, pulmonary, or tricuspid valve replacement.

Embodiments of the present disclosure are described herein below with reference to the accompanying drawings, in which some, but not all, embodiments are shown. Indeed, the prosthetic heart valves, delivery devices, and methods disclosed may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure is thorough and complete and fully conveys the scope of the prosthetic heart valves, delivery devices, and methods to those skilled in the art. Like reference numbers refer to like elements throughout. The singular forms “a,” “an,” and “the” can refer to plural instances unless the context clearly dictates otherwise or unless explicitly stated.

As described in detail below, the embodiments of the present disclosure provide improved prosthetic heart valves, delivery devices, and methods for replacing diseased or defective native heart valves, such as mitral valves, aortic valves, pulmonary valves, or tricuspid valves, of a native human heart. In particular, some embodiments of the prosthetic heart valve may be configured for mitral valve replacement and may be implanted via open heart surgery or less-invasive approaches, such as a transapical approach, a transatrial approach, a transfemoral approach, a transseptal approach, a subclavian approach, a direct aortic puncture approach, or other vascular access approaches. Such embodiments of the prosthetic heart valve may accommodate the shape and structure of the native mitral valve and the surrounding anatomy without compromising the integrity or function of the surrounding anatomy. Such embodiments of the prosthetic heart valve also may securely anchor onto the native heart tissue to prevent or inhibit migration of the prosthetic heart valve from the implantation site. Further, such embodiments of the prosthetic heart valve may form a seal against the native heart tissue to prevent or inhibit paravalvular leakage.

Although the following description focuses primarily on use of the prosthetic heart valve for mitral valve replace-

6

ment, it will be understood that some embodiments of the prosthetic heart valve may be configured for use in aortic, pulmonary, or tricuspid valve replacement. As will be appreciated by one of ordinary skill in the art, development of a prosthetic heart valve for replacement of the native mitral valve may present numerous technical and clinical challenges which must be taken in to account in order to provide a suitable prosthetic heart valve for mitral, aortic, pulmonary, or tricuspid valve replacement. For example, technical challenges and considerations include, but are not limited to, implanting the prosthetic heart valve at a narrow landing site on the native heart with limited imaging of the native heart anatomy and the prosthetic heart valve during implantation, navigating and accommodating the three-dimensional, dynamic native heart anatomy and complex sub-valvular features, accommodating the pressure gradient at the desired implantation site and the annular loads applied to the prosthetic heart valve by the native heart anatomy, providing adequate sealing against the native heart anatomy to prevent or inhibit paravalvular leakage, gaining access to the desired implantation site and guiding a relatively large prosthetic heart valve through the vasculature to the implantation site, avoiding undesirable thrombosis that may inhibit desired function of the prosthetic heart valve and/or surrounding features of the native heart, avoiding left ventricular outflow tract obstruction (LVOTO), and avoiding systolic anterior motion (SAM) of the mitral valve chordae tendinae. Clinical challenges and considerations include, but are not limited to, accommodating the particular complications of the sick population in need of valve replacement, identifying and addressing multiple and very different etiologies, such as ischemic, dilated cardiomyopathy, degenerative, and rheumatic etiologies, addressing an increased international normalized ratio (INR) because of thrombus potential including gastro-intestinal and other bleeds, and addressing atrial fibrillation.

According to one aspect, a prosthetic heart valve for replacing a diseased or defective native heart valve is provided. In one embodiment, the prosthetic heart valve may include an outer frame, an inner frame positioned at least partially within the outer frame, and an occluder member positioned at least partially within the inner frame. The prosthetic heart valve also may include an atrial flange extending from an atrial end of the outer frame, and a ventricular flange extending from a ventricular end of the outer frame, wherein at least a portion of the atrial flange extends radially outward beyond the ventricular flange.

In another embodiment, the prosthetic heart valve may include an outer frame having a D-shaped cross-sectional shape in a plane orthogonal to a longitudinal axis of the prosthetic heart valve, and an inner frame positioned at least partially within the outer frame and having a circular cross-sectional shape in the plane orthogonal to the longitudinal axis of the prosthetic heart valve. The prosthetic heart valve also may include an occluder member positioned at least partially within the inner frame, an atrial flange extending from an atrial end of the outer frame, and a ventricular flange extending from a ventricular end of the outer frame.

In still another embodiment, the prosthetic heart valve may include an expandable outer frame having a D-shaped cross-sectional shape in a plane orthogonal to a longitudinal axis of the prosthetic heart valve, and an expandable inner frame positioned at least partially within the outer frame and having a circular cross-sectional shape in the plane orthogonal to the longitudinal axis of the prosthetic heart valve. The prosthetic heart valve also may include an occluder member positioned at least partially within the inner frame, an atrial

flange extending from an atrial end of the outer frame, and a ventricular flange extending from a ventricular end of the outer frame, wherein at least a portion of the atrial flange extends radially outward beyond the ventricular flange.

Various aspects of the prosthetic heart valves, delivery devices, and methods described herein build upon those described in the following patent applications, which are incorporated by reference herein, in their entirety, for all purposes: U.S. application Ser. No. 11/888,009, filed Jul. 31, 2007; U.S. application Ser. No. 12/822,291, filed Jun. 24, 2010; U.S. application Ser. No. 13/339,236, filed Dec. 28, 2011; U.S. application Ser. No. 13/656,717, filed Oct. 21, 2012; U.S. application Ser. No. 13/772,203, filed Feb. 20, 2013; U.S. application Ser. No. 14/208,997, filed Mar. 13, 2014; U.S. application Ser. No. 14/278,594, filed May 15, 2014; PCT Application No. PCT/US2007/017061, filed Jul. 31, 2007; PCT Application No. PCT/US2011/067695, filed Dec. 29, 2011; PCT Application No. PCT/US2012/061292, filed Oct. 22, 2012; PCT Application No. PCT/US2013/027072, filed Feb. 21, 2013; and PCT Application No. PCT/US2014/038305, filed May 16, 2014. As will be appreciated by one of ordinary skill in the art, various features of the prosthetic heart valves, delivery devices, and methods described herein may be incorporated into the prosthetic heart valves, delivery devices, and methods described in the foregoing applications, and various features of the prosthetic heart valves, delivery devices, and methods described in the foregoing applications may be incorporated into the prosthetic heart valves, delivery devices, and methods described herein.

Referring now to the drawings, FIGS. 1A-1F illustrate an expandable prosthetic heart valve **100** (which also may be referred to as a “heart valve” or a “heart valve device”) according to one or more embodiments of the disclosure. In some embodiments, the prosthetic heart valve **100** may be configured for implantation at a diseased or defective native mitral valve of a human heart to replace the function of the native mitral valve. In other embodiments, the prosthetic heart valve **100** may be configured for implantation at a diseased or defective native aortic valve, pulmonary valve, or tricuspid valve of a human heart to replace the function of the native valve. As described below, the prosthetic heart valve **100** may accommodate the shape and structure of the native mitral valve and the surrounding anatomy without compromising the integrity or function of the surrounding anatomy, may securely anchor onto the native heart tissue to prevent or inhibit migration of the prosthetic heart valve **100** from the implantation site, and may form a seal against the native heart tissue to prevent or inhibit paravalvular leakage. Ultimately, the prosthetic heart valve **100** may restore desired function of the native heart by controlling blood flow in a manner similar to the native mitral valve being replaced.

The prosthetic heart valve **100** may be formed as a generally tubular structure having an elongated shape extending along a longitudinal axis of the heart valve **100**. The prosthetic heart valve **100** may be implanted within the native mitral valve such that the longitudinal axis of the prosthetic heart valve **100** is generally aligned with the longitudinal axis of the native mitral valve. When positioned at the desired implantation site, an end portion of the heart valve **100** may be positioned within the left atrium of the heart, another end portion of the heart valve **100** may be positioned within the left ventricle of the heart, and an intermediate portion of the heart valve **100** may be positioned within the annulus of the native mitral valve. In this manner, the prosthetic heart valve **100** may have an atrial end **102** (which also may be referred to as a “proximal end”

or a “first end”) and an ventricular end **104** (which also may be referred to as a “distal end” or a “second end”) positioned opposite the atrial end **102** along the longitudinal axis of the heart valve **100**. As described below, the prosthetic heart valve **100** may be expandable, such that the heart valve **100** may be moved between a collapsed state for delivery of the heart valve **100** to the desired implantation site and an expanded state for anchoring the heart valve **100** to the heart at the implantation site. In particular, the prosthetic heart valve **100** maybe configured for controlled expansion into one of a number of expanded states, such that the heart valve **100** may be expanded to an expanded state that corresponds to the size and shape of the anatomy of a particular patient. The prosthetic heart valve **100** also may be configured for controlled contraction from an expanded state toward or to the collapsed state, such that the heart valve **100** may be at least partially collapsed in order to reposition the heart valve **100** with respect to the heart anatomy, if necessary. In this manner, the prosthetic heart valve **100** may provide significant advantages over existing heart valves that are either self-expanding or are expanded by a balloon or other mechanism and do not provide a means for easily contracting or repositioning the heart valve.

The prosthetic heart valve **100** may include an outer frame **110** (which also may be referred to as a “radially outer frame”) and an inner frame **120** (which also may be referred to as a “radially inner frame”) positioned at least partially within the outer frame **110**. The outer frame **110** may be a generally tubular structure having an elongated shape extending along the longitudinal axis of the heart valve **100**. The outer frame **110** may be formed as a lattice or stent-like structure that radially expands and collapses as the prosthetic heart valve **100** is moved between the collapsed state and the expanded state. As shown, the lattice of the outer frame **110** may include a number of interconnected wire members **112** configured to deflect and/or articulate as the prosthetic heart valve **100** is moved between the collapsed state and the expanded state. The lattice of the outer frame **110** may be formed of a metal wire, although other materials and configurations of the lattice may be used. In some embodiments, the outer frame **110** may be formed of a shape memory alloy, such as nitinol, or a shape memory polymer, although other suitable metals, alloys, and polymers may be used. The lattice of the outer frame **110** may be configured such that controlled changes in the axial dimensions of the wire members **112** results in controlled changes to the orthogonal dimensions or diameter of the outer frame **110**. Changes to the dimensions of the lattice of the outer frame **110** may be prescribed by mechanical interaction between the wire members **112** and other mechanical elements, such as screws or rods, which may define different positions for specific points in the lattice and, in doing so, may define an axial length of the lattice and thus its resulting diameter. For example, the outer frame **110** may include a number of actuator members **114** configured to facilitate movement of the prosthetic heart valve **100** between the collapsed state and the expanded state. In some embodiments, as shown, the actuator members **114** may include a threaded rod received within a threaded tube. The actuator members **114** may be attached to a number of the wire members **112**, thereby forming a screw-jack mechanism to facilitate movement of the prosthetic heart valve **100** between the collapsed state and the expanded state. In other embodiments, the actuator members **114** may have other configurations for separately articulating the wire members **112** and selectively moving all or a portion of the prosthetic heart valve **100** between the collapsed state and the expanded state. In some embodi-

ments, the actuator elements are rods that have multiple points that generate mechanical interference with a selective locking element at different states of expansion or contraction. The outer frame **110** may have a longitudinal axis which may be coaxial with or spaced apart from the longitudinal axis of the prosthetic heart valve **100**. The outer frame **110** may have an atrial end **116** (which also may be referred to as a “proximal end” or a “first end”), and a ventricular end **118** (which also may be referred to as a “distal end” or a “second end”) positioned opposite the atrial end **116** along the longitudinal axis of the outer frame **110**.

The inner frame **120** may be a generally tubular structure having an elongated shape extending along the longitudinal axis of the heart valve **100**. The inner frame **120** also may be formed as a lattice or stent-like structure that radially expands and collapses as the prosthetic heart valve **100** is moved between the collapsed state and the expanded state. As shown, the lattice of the inner frame **120** may include a number of interconnected wire members **122** configured to deflect and/or articulate as the prosthetic heart valve **100** is moved between the collapsed state and the expanded state. The lattice of the inner frame **120** may be formed of a deformable metal wire, although other materials and configurations of the lattice may be used. In some embodiments, the inner frame **120** may be formed of a shape memory alloy, such as nitinol, or a shape memory polymer, although other suitable metals, alloys, and polymers may be used. The inner frame **120** may have a longitudinal axis which may be coaxial with or spaced apart from the longitudinal axis of the prosthetic heart valve **100** and which may be coaxial with or spaced apart from the longitudinal axis of the outer frame **110**. The inner frame **120** may have an atrial end **126** (which also may be referred to as a “proximal end” or a “first end”), and a ventricular end **128** (which also may be referred to as a “distal end” or a “second end”) positioned opposite the atrial end **126** along the longitudinal axis of the inner frame **120**. As shown, the atrial end **126** of the inner frame **120** may be positioned within the lumen of the outer frame **110**, and the ventricular end **128** of the inner frame **120** may be positioned outside of the lumen of the outer frame **110**. In some embodiments, as shown, the ventricular end **128** of the inner frame **120** may be positioned at the ventricular end **104** of the prosthetic heart valve **100**.

The outer frame **110** and the inner frame **120** may have a variety of cross-sectional shapes in a plane orthogonal to the longitudinal axes thereof. In various embodiments, the outer frame **110** may have a circular shape, an elliptical shape, a “D”-shape, a square shape, a rectangular shape, a polygonal shape, a curved shape, or a shape having one or more curved sections and one or more straight sections in the plane orthogonal to the longitudinal axis of the outer frame **110**. In some embodiments, the cross-sectional shape of the outer frame **110** may be constant along the longitudinal direction. In other embodiments, the cross-sectional shape of the outer frame **110** may vary along the longitudinal direction. In some embodiments, the size of the cross-sectional shape of the outer frame **110** may be constant along the longitudinal direction. In other embodiments, the size of the cross-sectional shape of the outer frame **110** may vary along the longitudinal direction. In various embodiments, the inner frame **120** may have a circular shape, an elliptical shape, a “D”-shape, a square shape, a rectangular shape, a polygonal shape, a curved shape, or a shape having one or more curved sections and one or more straight sections in the plane orthogonal to the longitudinal axis of the inner frame **120**. In some embodiments, the cross-sectional shape of the inner

frame **120** may be constant along the longitudinal direction. In other embodiments, the cross-sectional shape of the inner frame **120** may vary along the longitudinal direction. In some embodiments, the size of the cross-sectional shape of the inner frame **120** may be constant along the longitudinal direction. In other embodiments, the size of the cross-sectional shape of the inner frame **120** may vary along the longitudinal direction. In some embodiments, the outer frame **110** may have a “D”-shape and the inner frame **120** may have a circular shape. In this manner, the outer frame **110** may be shaped to accommodate the generally “D”-shape of the native mitral valve, while the inner frame **120** may be shaped to accommodate an occluder member, such as a multi-leaflet valve, having a generally circular shape. Notably, use of the “D”-shaped outer frame **110** may reduce the possibility of left ventricular outflow tract obstruction. In other embodiments, the outer frame **110** may have a circular shape and the inner frame **120** may have a circular shape. In still other embodiments, the outer frame **110** and the inner frame **120** may have other shapes, which may be the same as or different from one another. In some embodiments, the outer frame **110** and the inner frame **120** may have the same longitudinal heights, although different longitudinal heights of the outer frame **110** and the inner frame **120** may be used in other embodiments.

As shown, the outer frame **110** and the inner frame **120** may be connected to one another by a trampoline **130** (which also may be referred to as an “intermediate frame” or an “intermediate support”) that extends radially between the outer frame **110** and the inner frame **120**. In this manner, the trampoline **130** may maintain a relative position of the inner frame **120** with respect to the outer frame **110** and may guide the inner frame **120** during expansion and contraction of the prosthetic heart valve **100**. In particular, the trampoline **130** may transfer forces from the outer frame **110** to the inner frame **120** as the outer frame **110** is expanded or collapsed, thereby causing the inner frame **120** to expand or collapse in a similar manner. As shown, the trampoline **130** may be formed as a lattice including a number of interconnected wire members **132** configured to deflect and/or articulate as the prosthetic heart valve **100** is moved between the collapsed state and the expanded state. The trampoline **130** may provide a contoured transition between the outer frame **110** and the inner frame **120**, particularly when the outer frame **110** and the inner frame **120** have different cross-sectional shapes. In some embodiments, the trampoline **130** may be attached to the outer frame **110** and the inner frame **120** by mechanical fasteners, welding, soldering, bonding, chemical bonding or attachment, or other suitable means of attachment. In other embodiments, the outer frame **110**, the inner frame **120**, and the trampoline **130** may be formed from a single piece of material, which may be bent to form the respective shapes of the outer frame **110**, the inner frame **120**, and the trampoline **130**.

As shown, the prosthetic heart valve **100** also may include a pair of flanges attached to the outer frame **110**. In particular, the prosthetic heart valve **100** may include an atrial flange **140** (which also may be referred to as an “atrial skirt,” a “proximal flange,” a “proximal skirt,” or an “extended sealing surface”) attached to the atrial end **116** of the outer frame **110** and extending axially and/or radially outward therefrom. In some embodiments, the atrial flange **140** may be spaced apart from and positioned along the outer surface of the outer frame **110** distally from the atrial end **116** of the outer frame **110**. During implantation of the prosthetic heart valve **100**, the atrial flange **140** may be positioned within the left atrium of the heart and in apposition against a tissue

surface therein above the mitral valve annulus. The atrial flange **140** may be flexible such that the atrial flange **140** may be collapsed and expanded along with the outer frame **110** to facilitate positioning and anchoring of the outer frame **110** at the implantation site. As shown, the atrial flange **140** may include a number of petals **142** positioned in a circumferential array along the circumference of the outer frame **110**. The petals **142** may be formed of a metal or polymer wire, although other materials and configurations of the petals **142** may be used. In some embodiments, the petals **142** may be formed of wire mesh or stent lattice.

The prosthetic heart valve **100** also may include a ventricular flange **150** (which also may be referred to as a “ventricular skirt,” a “distal flange,” a “distal skirt,” or an “extended sealing surface”) attached to the ventricular end **118** of the outer frame **110** and extending axially and radially outward therefrom. In some embodiments, the ventricular flange **150** may be spaced apart from and positioned along the outer surface of the outer frame **110** proximally from the ventricular end **118** of the outer frame **110**. During implantation of the prosthetic heart valve **100**, the ventricular flange **150** may be positioned within the left ventricle of the heart and in apposition against a tissue surface therein below the mitral valve annulus. The ventricular flange **150** may be flexible such that the ventricular flange **150** may be collapsed and expanded along with the outer frame **110** to facilitate positioning and anchoring of the outer frame **110** at the implantation site. As shown, the ventricular flange **150** may include a number of petals **152** positioned in a circumferential array along the circumference of the outer frame **110**. The petals **152** may be formed of a metal or polymer wire, although other materials and configurations of the petals **152** may be used. In some embodiments, the petals **152** may be formed of wire mesh or stent lattice.

Notably, the atrial flange **140** and the ventricular flange **150** may facilitate mechanical interference based anchoring of the prosthetic heart valve **100** onto the heart as well as pressure-driven sealing between the heart valve **100** and the mating heart tissue. Such anchoring and sealing benefits may be particularly advantageous in mitral valve replacement because the presence of the left ventricular outflow tract, the more compliant tissue, the shorter annuli, and the increased area of dilated annuli do not allow for reliance only on radial force for sealing and anchoring, as in aortic valve replacement. In some embodiments, the ventricular flange **150** may be larger than the atrial flange **140**, such that the ventricular flange **150** has a larger cross-sectional area than the atrial flange **140** in the plane orthogonal to the longitudinal axis of the. In some embodiments, at least a portion of the ventricular flange **150** may extend radially outward beyond the atrial flange **140**. In other embodiments, the ventricular flange **150** may extend radially outward beyond the atrial flange **140** along the entire circumference of the flanges **140**, **150**. In some embodiments, all of the petals **142** of the atrial flange **140** may have the same size, with the same axial length and the same radial length. In other embodiments, the petals **142** of the atrial flange **140** may vary in their axial length and/or their radial length along the circumference of the atrial flange **140**. In some embodiments, one or more of the petals **142** configured to be positioned at or near the trigones of the mitral valve may be stiffer and/or longer than a remainder of the petals **142**. In this manner, such embodiments may provide enhanced anchoring about the trigones of the mitral valve. In some embodiments, all of the petals **152** of the ventricular flange **150** may have the same size, with the same axial length and the same radial length. In other embodiments, the petals **152**

of the ventricular flange **150** may vary in their axial length and/or their radial length along the circumference of the ventricular flange **150**. In some embodiments, one or more of the petals **152** configured to be positioned at or near the trigones of the mitral valve may be stiffer and/or longer than a remainder of the petals **152**. In this manner, such embodiments may provide enhanced anchoring about the trigones of the mitral valve.

As shown, the prosthetic heart valve **100** may include a biocompatible covering **160** (which also may be referred to as a “membrane”) positioned over portions of the outer frame **110**, the inner frame **120**, the trampoline **130**, the atrial flange **140**, and/or the ventricular flange **150**. The outer frame **110**, the inner frame **120**, the trampoline **130**, the atrial flange **140**, and/or the ventricular flange **150** each may be partially or entirely covered by the covering **160**, according to various embodiments. The covering **160** may be formed as a single component positioned over the respective portions of the heart valve **100** or as multiple components positioned over the respective portions of the heart valve **100**. In some embodiments, the covering **160** extends over the outer surfaces and/or the inner surfaces of the outer frame **110**, the inner frame **120**, the trampoline **130**, the atrial flange **140**, and/or the ventricular flange **150**. In some embodiments, the covering **160** is formed of a biocompatible cloth or textile material, although other suitable materials may be used for the covering **160**. When the prosthetic heart valve **100** is implanted, the covering **160** may promote hemostasis at the implantation site, preventing or inhibiting blood flow around the heart valve **100**. The covering **160** also may promote tissue ingrowth or overgrowth to facilitate anchoring of the prosthetic heart valve **100** to the heart tissue.

The prosthetic heart valve **100** further may include an occluder member **170** (which also may be referred to simply as an “occluder”) attached to the inner frame **120** and positioned at least partially within the lumen thereof. The occluder member **170** may be configured to control blood flow through the prosthetic heart valve **100** in a manner similar to the native heart valve being replaced. In some embodiments, as shown, the occluder member **170** may be a multi-leaflet valve including a number of leaflets **172** arranged to form a one-way valve to control blood flow therebetween. The leaflets **172** may be formed of a metal, a polymer, a ceramic, a composite material, or a bioprosthetic material. For example, the leaflets **172** may be bioprosthetic leaflets of treated animal tissue, such as porcine, bovine, or equine tissue. In other embodiments, the occluder member **170** may include one or more spheres, one or more discs, one or more rotating plates, or other types of members configured to control blood flow. Any such embodiments may be configured as a one-directional occluder member, allowing blood flow therethrough in one direction and preventing blood flow in an opposite direction.

In some embodiments, the prosthetic heart valve **100** also may include one or more anchors attached to the outer frame **110** and extending radially outward therefrom. During implantation of the prosthetic heart valve **100**, the anchors may be configured to pierce or create a mechanical interference with the surrounding heart tissue, such as the native mitral valve annulus. In this manner, the anchors may further secure the position of the prosthetic heart valve **100** at the implantation site. In some embodiments, the anchors may be fixed relative to the outer frame **110** and may engage the surrounding heart tissue as the prosthetic heart valve **100** is expanded within the native mitral valve. In other embodiments, the anchors may be deployed from a retracted state

for positioning of the prosthetic heart valve **100** to a deployed state for engaging the surrounding heart tissue. In some embodiments, the anchors may be formed as prongs or hooks, although other configurations of the anchors may be used.

The prosthetic heart valve **100** may be delivered to the desired implantation site and anchored to the native heart via a delivery device **180**. As shown, the delivery device **180** may include a shaft **182** with a guide tip **184** attached to a distal end of the shaft **182**. During use of the delivery device **180**, the guide tip **184** and a distal portion of the shaft **182** may extend through the prosthetic heart valve **100**, as shown, to guide the prosthetic heart valve **100** through the vasculature to the implantation site. The delivery device **180** also may include a sheath positioned over the shaft **182** and configured to retain the prosthetic heart valve **100** in the collapsed state therein until the distal end portion of the delivery device **180** reaches the implantation site. The sheath then may be retracted to expose the prosthetic heart valve **100**. The delivery device **180** also may include a number of control wires **186** configured to attach to the actuator members **114** of the outer frame **110**. In some embodiments, the control wires **186** may be threaded and configured to threadably attach to the actuator members **114**, although other means of attachment may be used. After the prosthetic heart valve **100** is exposed and positioned within the native mitral valve, the control wires **186** may be manipulated to actuate the actuator members **114**, thereby causing the outer frame **110** to controllably expand from the collapsed state. As described above, expansion of the outer frame **110** also may cause the inner frame **120** to expand. The prosthetic heart valve **100** may be expanded in this manner within the native mitral valve until the outer surface of the outer frame **110** sufficiently engages the native mitral valve annulus to maintain a relative position of the prosthetic heart valve **100** with respect to the native mitral valve. Upon such expansion, the anchors, if present, may engage the mitral valve annulus or other heart tissue. Meanwhile, the ventricular flange **150** may expand within the left ventricle of the heart and engage the tissue surface below the mitral valve annulus. Once the desired positioning of the prosthetic heart valve **100** within the native mitral valve is obtained, the control wires **186** may be disengaged from the actuator members **114**. Upon disengaging the control wires **186**, the atrial flange **140** may expand within the left atrium and engage the tissue surface above the mitral valve annulus. Ultimately, the engagement between the outer frame **110** and the mitral valve annulus, the engagement between the ventricular flange **150** and the mating tissue surface, and the engagement between the atrial flange **140** and the mating tissue surface may securely anchor the prosthetic heart valve **100** within the native mitral valve. In embodiments that include the anchors, the engagement between the anchors and the mating tissue may further anchor the prosthetic heart valve **100**. Meanwhile, the engagement between the covering **160** and the mating tissue surfaces, the engagement between the ventricular flange **150** and the mating tissue surface, and the engagement between the atrial flange **140** and the mating tissue surface may provide one or more seals that prevent or inhibit blood flow around the prosthetic heart valve **100** and also may promote tissue ingrowth or overgrowth to further seal and anchor the prosthetic heart valve **100**. The prosthetic heart valve **100** described herein may be configured for anchoring onto a mitral valve annulus having a commissural diameter in the range of between 2 cm and 7 cm, which may cover a majority of patients in need of heart valve replacement.

FIGS. 2A-2J illustrate an expandable prosthetic heart valve **200** (which also may be referred to as a “heart valve” or a “heart valve device”) according to one or more embodiments of the disclosure. In some embodiments, the prosthetic heart valve **200** may be configured for implantation at a diseased or defective native mitral valve of a human heart to replace the function of the native mitral valve. In other embodiments, the prosthetic heart valve **200** may be configured for implantation at a diseased or defective native aortic valve, pulmonary valve, or tricuspid valve of a human heart to replace the function of the native valve. As described below, the prosthetic heart valve **200** may accommodate the shape and structure of the native mitral valve and the surrounding anatomy without compromising the integrity or function of the surrounding anatomy, may securely anchor onto the native heart tissue to prevent or inhibit migration of the prosthetic heart valve **200** from the implantation site, and may form a seal against the native heart tissue to prevent or inhibit paravalvular leakage. Ultimately, the prosthetic heart valve **200** may restore desired function of the native heart by controlling blood flow in a manner similar to the native mitral valve being replaced.

The prosthetic heart valve **200** may be formed as a generally tubular structure having an elongated shape extending along a longitudinal axis of the heart valve **200**. The prosthetic heart valve **200** may be implanted within the native mitral valve such that the longitudinal axis of the prosthetic heart valve **200** is generally aligned with the longitudinal axis of the native mitral valve. When positioned at the desired implantation site, an end portion of the heart valve **200** may be positioned within the left atrium of the heart, another end portion of the heart valve **200** may be positioned within the left ventricle of the heart, and an intermediate portion of the heart valve **200** may be positioned within the annulus of the native mitral valve. In this manner, the prosthetic heart valve **200** may have an atrial end **202** (which also may be referred to as a “proximal end” or a “first end”) and a ventricular end **204** (which also may be referred to as a “distal end” or a “second end”) positioned opposite the atrial end **202** along the longitudinal axis of the heart valve **200**. As described below, the prosthetic heart valve **200** may be expandable, such that the heart valve **200** may be moved between a collapsed state for delivery of the heart valve **200** to the desired implantation site and an expanded state for anchoring the heart valve **200** to the heart at the implantation site. In particular, the prosthetic heart valve **200** may be configured for controlled expansion into one of a number of expanded states, such that the heart valve **200** may be expanded to an expanded state that corresponds to the size and shape of the anatomy of a particular patient. The prosthetic heart valve **200** also may be configured for controlled contraction from an expanded state toward or to the collapsed state, such that the heart valve **200** may be at least partially collapsed in order to reposition the heart valve **200** with respect to the heart anatomy, if necessary. In this manner, the prosthetic heart valve **200** may provide significant advantages over existing heart valves that are either self-expanding or are expanded by a balloon or other mechanism and do not provide a means for easily contracting or repositioning the heart valve.

The prosthetic heart valve **200** may include an outer frame **210** (which also may be referred to as a “radially outer frame”) and an inner frame **220** (which also may be referred to as a “radially inner frame”) positioned at least partially within the outer frame **210**. The outer frame **210** may be a generally tubular structure having an elongated shape extending along the longitudinal axis of the heart valve **200**.

15

The outer frame **210** may be formed as a lattice or stent-like structure that radially expands and collapses as the prosthetic heart valve **200** is moved between the collapsed state and the expanded state. As shown, the lattice of the outer frame **210** may include a number of interconnected wire members **212** configured to deflect and/or articulate as the prosthetic heart valve **200** is moved between the collapsed state and the expanded state. The lattice of the outer frame **210** may be formed of a metal wire, although other materials and configurations of the lattice may be used. In some embodiments, the outer frame **210** may be formed of a shape memory alloy, such as nitinol, or a shape memory polymer, although other suitable metals, alloys, and polymers may be used. The lattice of the outer frame **210** may be configured such that controlled changes in the axial dimensions of the wire members **212** results in controlled changes to the orthogonal dimensions or diameter of the outer frame **210**. Changes to the dimensions of the lattice of the outer frame **210** may be prescribed by mechanical interaction between the wire members **212** and other mechanical elements, such as screws or rods, which may define different positions for specific points in the lattice and, in doing so, may define an axial length of the lattice and thus its resulting diameter. For example, the outer frame **210** may include a number of actuator members **214** configured to facilitate movement of the prosthetic heart valve **200** between the collapsed state and the expanded state. In some embodiments, as shown, the actuator members **214** may include a threaded rod received within a threaded tube. The actuator members **214** may be attached to a number of the wire members **212**, thereby forming a screw-jack mechanism to facilitate movement of the prosthetic heart valve **200** between the collapsed state and the expanded state. In other embodiments, the actuator members **214** may have other configurations for articulating the wire members **212** and moving the prosthetic heart valve **200** between the collapsed state and the expanded state. The outer frame **210** may have a longitudinal axis which may be coaxial with or spaced apart from the longitudinal axis of the prosthetic heart valve **200**. The outer frame **210** may have an atrial end **216** (which also may be referred to as a “proximal end” or a “first end”), and a ventricular end **218** (which also may be referred to as a “distal end” or a “second end”) positioned opposite the atrial end **216** along the longitudinal axis of the outer frame **210**.

The inner frame **220** may be a generally tubular structure having an elongated shape extending along the longitudinal axis of the heart valve **200**. The inner frame **220** also may be formed as a lattice or stent-like structure that radially expands and collapses as the prosthetic heart valve **200** is moved between the collapsed state and the expanded state. As shown, the lattice of the inner frame **220** may include a number of interconnected wire members **222** configured to deflect and/or articulate as the prosthetic heart valve **200** is moved between the collapsed state and the expanded state. The lattice of the inner frame **220** may be formed of a deformable metal wire, although other materials and configurations of the lattice may be used. In some embodiments, the inner frame **220** may be formed of a shape memory alloy, such as nitinol, or a shape memory polymer, although other suitable metals, alloys, and polymers may be used. The inner frame **220** may have a longitudinal axis which may be coaxial with or spaced apart from the longitudinal axis of the prosthetic heart valve **200** and which may be coaxial with or spaced apart from the longitudinal axis of the outer frame **210**. The inner frame **220** may have an atrial end **226** (which also may be referred to as a “proximal end” or a “first end”), and a ventricular end **228**

16

(which also may be referred to as a “distal end” or a “second end”) positioned opposite the atrial end **226** along the longitudinal axis of the inner frame **220**. As shown, the atrial end **226** of the inner frame **220** may be positioned within the lumen of the outer frame **210**, and the ventricular end **228** of the inner frame **220** may be positioned outside of the lumen of the outer frame **210**. In some embodiments, as shown, the ventricular end **228** of the inner frame **220** may be positioned at the ventricular end **204** of the prosthetic heart valve **200**.

The outer frame **210** and the inner frame **220** may have a variety of cross-sectional shapes in a plane orthogonal to the longitudinal axes thereof. In various embodiments, the outer frame **210** may have a circular shape, an elliptical shape, a “D”-shape, a square shape, a rectangular shape, a polygonal shape, a curved shape, or a shape having one or more curved sections and one or more straight sections in the plane orthogonal to the longitudinal axis of the outer frame **210**. In some embodiments, the cross-sectional shape of the outer frame **210** may be constant along the longitudinal direction. In other embodiments, the cross-sectional shape of the outer frame **210** may vary along the longitudinal direction. In some embodiments, the size of the cross-sectional shape of the outer frame **210** may be constant along the longitudinal direction. In other embodiments, the size of the cross-sectional shape of the outer frame **210** may vary along the longitudinal direction. In various embodiments, the inner frame **220** may have a circular shape, an elliptical shape, a “D”-shape, a square shape, a rectangular shape, a polygonal shape, a curved shape, or a shape having one or more curved sections and one or more straight sections in the plane orthogonal to the longitudinal axis of the inner frame **220**. In some embodiments, the cross-sectional shape of the inner frame **220** may be constant along the longitudinal direction. In other embodiments, the cross-sectional shape of the inner frame **220** may vary along the longitudinal direction. In some embodiments, the size of the cross-sectional shape of the inner frame **220** may be constant along the longitudinal direction. In other embodiments, the size of the cross-sectional shape of the inner frame **220** may vary along the longitudinal direction. In some embodiments, the outer frame **210** may have a “D”-shape and the inner frame **220** may have a circular shape. In this manner, the outer frame **210** may be shaped to accommodate the generally “D”-shape of the native mitral valve, while the inner frame **220** may be shaped to accommodate an occluder member, such as a multi-leaflet valve, having a generally circular shape. Notably, use of the “D”-shaped outer frame **210** may reduce the possibility of left ventricular outflow tract obstruction. In other embodiments, the outer frame **210** may have a circular shape and the inner frame **220** may have a circular shape. In still other embodiments, the outer frame **210** and the inner frame **220** may have other shapes, which may be the same as or different from one another. In some embodiments, the outer frame **210** and the inner frame **220** may have the same longitudinal heights, although different longitudinal heights of the outer frame **210** and the inner frame **220** may be used in other embodiments.

As shown, the outer frame **210** and the inner frame **220** may be connected to one another by a trampoline **230** (which also may be referred to as an “intermediate frame” or an “intermediate support”) that extends radially between the outer frame **210** and the inner frame **220**. In this manner, the trampoline **230** may maintain a relative position of the inner frame **220** with respect to the outer frame **210** and may guide the inner frame **220** during expansion and contraction of the prosthetic heart valve **200**. In particular, the trampoline **230**

may transfer forces from the outer frame 210 to the inner frame 220 as the outer frame 210 is expanded or collapsed, thereby causing the inner frame 220 to expand or collapse in a similar manner. As shown, the trampoline 230 may be formed as a lattice including a number of interconnected wire members 232 configured to deflect and/or articulate as the prosthetic heart valve 200 is moved between the collapsed state and the expanded state. The trampoline 230 may provide a contoured transition between the outer frame 210 and the inner frame 220, particularly when the outer frame 210 and the inner frame 220 have different cross-sectional shapes. In some embodiments, the trampoline 230 may be attached to the outer frame 210 and the inner frame 220 by mechanical fasteners, welding, soldering, bonding, chemical bonding or attachment, or other suitable means of attachment. In other embodiments, the outer frame 210, the inner frame 220, and the trampoline 230 may be formed from a single piece of material, which may be bent to form the respective shapes of the outer frame 210, the inner frame 220, and the trampoline 230.

As shown, the prosthetic heart valve 200 also may include a pair of flanges attached to the outer frame 210. In particular, the prosthetic heart valve 200 may include an atrial flange 240 (which also may be referred to as an "atrial skirt," a "proximal flange," a "proximal skirt," or an "extended sealing surface") attached to the atrial end 216 of the outer frame 210 and extending axially and/or radially outward therefrom. In some embodiments, the atrial flange 240 may be spaced apart from and positioned along the outer surface of the outer frame 210 distally from the atrial end 216 of the outer frame 210. During implantation of the prosthetic heart valve 200, the atrial flange 240 may be positioned within the left atrium of the heart and in apposition against a tissue surface therein above the mitral valve annulus. The atrial flange 240 may be flexible such that the atrial flange 240 may be collapsed and expanded along with the outer frame 210 to facilitate positioning and anchoring of the outer frame 210 at the implantation site. As shown, the atrial flange 240 may include a number of petals 242 positioned in a circumferential array along the circumference of the outer frame 210. The petals 242 may be formed of a metal or polymer wire, although other materials and configurations of the petals 242 may be used. In some embodiments, the petals 242 may be formed of wire mesh or stent lattice.

The prosthetic heart valve 200 also may include a ventricular flange 250 (which also may be referred to as a "ventricular skirt," a "distal flange," a "distal skirt," or an "extended sealing surface") attached to the ventricular end 218 of the outer frame 210 and extending axially and radially outward therefrom. In some embodiments, the ventricular flange 250 may be spaced apart from and positioned along the outer surface of the outer frame 210 proximally from the ventricular end 218 of the outer frame 210. During implantation of the prosthetic heart valve 200, the ventricular flange 250 may be positioned within the left ventricle of the heart and in apposition against a tissue surface therein below the mitral valve annulus. The ventricular flange 250 may be flexible such that the ventricular flange 250 may be collapsed and expanded along with the outer frame 210 to facilitate positioning and anchoring of the outer frame 210 at the implantation site. As shown, the ventricular flange 250 may include a number of petals 252 positioned in a circumferential array along the circumference of the outer frame 210. The petals 252 may be formed of a metal or polymer wire, although other materials and configurations of the petals 252 may be used. In some embodiments, the petals 252 may be formed of wire mesh or stent lattice.

Notably, the atrial flange 240 and the ventricular flange 250 may facilitate mechanical interference based anchoring of the prosthetic heart valve 200 onto the heart as well as pressure-driven sealing between the heart valve 200 and the mating heart tissue. Such anchoring and sealing benefits may be particularly advantageous in mitral valve replacement because the presence of the left ventricular outflow tract, the more compliant tissue, the shorter annuli, and the increased area of dilated annuli do not allow for reliance only on radial force for sealing and anchoring, as in aortic valve replacement. In some embodiments, the ventricular flange 250 may be larger than the atrial flange 240, such that the ventricular flange 250 has a larger cross-sectional area than the atrial flange 240 in the plane orthogonal to the longitudinal axis of the. In some embodiments, at least a portion of the ventricular flange 250 may extend radially outward beyond the atrial flange 240. In other embodiments, the ventricular flange 250 may extend radially outward beyond the atrial flange 240 along the entire circumference of the flanges 240, 250. In some embodiments, all of the petals 242 of the atrial flange 240 may have the same size, with the same axial length and the same radial length. In other embodiments, the petals 242 of the atrial flange 240 may vary in their axial length and/or their radial length along the circumference of the atrial flange 240. In some embodiments, one or more of the petals 242 configured to be positioned at or near the trigones of the mitral valve may be stiffer and/or longer than a remainder of the petals 242. In this manner, such embodiments may provide enhanced anchoring about the trigones of the mitral valve. In some embodiments, the petals on the anterior section of the valve which lie between the trigones may be shorter or have another preferential shapes, so as to interfere less with the aortic root. In some embodiments, all of the petals 252 of the ventricular flange 250 may have the same size, with the same axial length and the same radial length. In other embodiments, the petals 252 of the ventricular flange 250 may vary in their axial length and/or their radial length along the circumference of the ventricular flange 250. In some embodiments, one or more of the petals 252 configured to be positioned at or near the trigones of the mitral valve may be stiffer and/or longer than a remainder of the petals 252. In this manner, such embodiments may provide enhanced anchoring about the trigones of the mitral valve. In some embodiments, the petals or any other anchor in the commissural areas in the atrial and/or ventricular sides of the valve, may be configured by location or shape to pass partially or fully between the leaflets, at the commissural edge in order to interfere minimally with leaflet motion.

As shown, the prosthetic heart valve 200 may include a biocompatible covering 260 (which also may be referred to as a "membrane") positioned over portions of the outer frame 210, the inner frame 220, the trampoline 230, the atrial flange 240, and/or the ventricular flange 250. The outer frame 210, the inner frame 220, the trampoline 230, the atrial flange 240, and/or the ventricular flange 250 each may be partially or entirely covered by the covering 260, according to various embodiments. The covering 260 may be formed as a single component positioned over the respective portions of the heart valve 200 or as multiple components positioned over the respective portions of the heart valve 200. In some embodiments, the covering 260 extends over the outer surfaces and/or the inner surfaces of the outer frame 210, the inner frame 220, the trampoline 230, the atrial flange 240, and/or the ventricular flange 250. In some embodiments, the covering 260 is formed of a biocompatible cloth or textile material, although other suitable mate-

rials may be used for the covering **260**. When the prosthetic heart valve **200** is implanted, the covering **260** may promote hemostasis at the implantation site, preventing or inhibiting blood flow around the heart valve **200**. The covering **260** also may promote tissue ingrowth or overgrowth to facilitate

anchoring of the prosthetic heart valve **200** to the heart tissue.

The prosthetic heart valve **200** further may include an occluder member **270** (which also may be referred to simply as an “occluder”) attached to the inner frame **220** and positioned at least partially within the lumen thereof. The occluder member **270** may be configured to control blood flow through the prosthetic heart valve **200** in a manner similar to the native heart valve being replaced. In some embodiments, as shown, the occluder member **270** may be a multi-leaflet valve including a number of leaflets **272** arranged to form a one-way valve to control blood flow therebetween. The leaflets **272** may be formed of a metal, a polymer, a ceramic, a composite material, or a bioprosthetic material. For example, the leaflets **272** may be bioprosthetic leaflets of treated animal tissue, such as porcine, bovine, or equine tissue. In other embodiments, the occluder member **270** may include one or more spheres, one or more discs, one or more rotating plates, or other types of members configured to control blood flow. Any such embodiments may be configured as a one-directional occluder member, allowing blood flow therethrough in one direction and preventing blood flow in an opposite direction.

In some embodiments, the prosthetic heart valve **200** also may include one or more anchors **274** attached to the outer frame **210** and extending radially outward therefrom. During implantation of the prosthetic heart valve **200**, the anchors **274** may be configured to pierce or create a mechanical interference with the surrounding heart tissue, such as the native mitral valve annulus. In this manner, the anchors **274** may further secure the position of the prosthetic heart valve **200** at the implantation site. In some embodiments, the anchors **274** may be fixed relative to the outer frame **210** and may engage the surrounding heart tissue as the prosthetic heart valve **200** is expanded within the native mitral valve. In other embodiments, as shown, the anchors **274** may be deployed from a retracted state for positioning of the prosthetic heart valve **200** to a deployed state for engaging the surrounding heart tissue. In some embodiments, the anchors **274** may be formed as prongs or hooks, although other configurations of the anchors may be used.

The prosthetic heart valve **200** may be delivered to the desired implantation site and anchored to the native heart via a delivery device **280**. As shown, the delivery device **280** may include a shaft **282** with a guide tip **284** attached to a distal end of the shaft **282**. During use of the delivery device **280**, the guide tip **284** and a distal portion of the shaft **282** may extend through the prosthetic heart valve **200**, as shown, to guide the prosthetic heart valve **200** through the vasculature to the implantation site. The delivery device **280** also may include a sheath positioned over the shaft **282** and configured to retain the prosthetic heart valve **200** in the collapsed state therein until the distal end portion of the delivery device **280** reaches the implantation site. The sheath then may be retracted to expose the prosthetic heart valve **200**. The delivery device **280** also may include a number of control wires **286** configured to attach to the actuator members **214** of the outer frame **210**. In some embodiments, the control wires **286** may be threaded and configured to threadably attach to the actuator members **214**, although other means of attachment may be used. After the prosthetic heart valve **200** is exposed and positioned within the native mitral

valve, the control wires **286** may be manipulated to actuate the actuator members **214**, thereby causing the outer frame **210** to controllably expand from the collapsed state. As described above, expansion of the outer frame **210** also may cause the inner frame **220** to expand. The prosthetic heart valve **200** may be expanded in this manner within the native mitral valve until the outer surface of the outer frame **210** sufficiently engages the native mitral valve annulus to maintain a relative position of the prosthetic heart valve **200** with respect to the native mitral valve. Upon such expansion, the anchors **274**, if present, may engage the mitral valve annulus or other heart tissue. Meanwhile, the ventricular flange **250** may expand within the left ventricle of the heart and engage the tissue surface below the mitral valve annulus. Once the desired positioning of the prosthetic heart valve **200** within the native mitral valve is obtained, the control wires **286** may be disengaged from the actuator members **214**. Upon disengaging the control wires **286**, the atrial flange **240** may expand within the left atrium and engage the tissue surface above the mitral valve annulus. Ultimately, the engagement between the outer frame **210** and the mitral valve annulus, the engagement between the ventricular flange **250** and the mating tissue surface, and the engagement between the atrial flange **240** and the mating tissue surface may securely anchor the prosthetic heart valve **200** within the native mitral valve. In embodiments that include the anchors **274**, the engagement between the anchors **274** and the mating tissue may further anchor the prosthetic heart valve **200**. Meanwhile, the engagement between the covering **260** and the mating tissue surfaces, the engagement between the ventricular flange **250** and the mating tissue surface, and the engagement between the atrial flange **240** and the mating tissue surface may provide one or more seals that prevent or inhibit blood flow around the prosthetic heart valve **200** and also may promote tissue ingrowth or overgrowth to further seal and anchor the prosthetic heart valve **200**. The prosthetic heart valve **200** described herein may be configured for anchoring onto a mitral valve annulus having a commissural diameter in the range of between 2 cm and 7 cm, which may cover a majority of patients in need of heart valve replacement.

FIGS. 3A-3F show an exemplary method for controllably delivering an expandable mitral valve with a double frame of an embodiment of the present invention. FIG. 3A shows the approach to the mitral valve. FIG. 3B shows unsheathing of the ventricular skirt. FIG. 3C shows controlled expansion of the frame, allowing repositioning or re-sheathing by contracting the frame. FIG. 3D shows the atrial petals open for positioning and hemodynamic function verification. Repositioning can be achieved by contracting the frame. Re-sheathing can be achieved by contracting the frame and bringing in the petals with control wires. FIG. 3E shows two views of releasing the control wires in the final position. FIG. 3F shows two views of removing the guide wire and final verification of the valve position and function.

In some embodiments, the steps described in FIGS. 3A-3F may be used to deploy the valve, in the proposed sequence or in another sequence of steps. The delivery may be transatrial, trans-apical, venous, trans-septal or any other vascular or non-vascular route. In one embodiment the system may be electromechanical and computer controlled in order to facilitate the steps for delivery, deployment, anchoring, re-sheathing and release.

FIGS. 3G-3L show a method for controlled re-sheathing of an expandable mitral valve with petals of an embodiment of the present invention. FIG. 3G illustrates how a single button operation minimizes complexity in re-sheathing atrial

21

petals after deployment. FIG. 3H shows how control wires pass outside or within slots in atrial petals to enable inward deflection. FIG. 3I shows coordinated contraction of stent and forward motion of sheath allow for petals to be retracted into the frame. FIG. 3J shows that at minimum driven size, the sheath moves forward and can pass over a funneled ventricular skirt. FIG. 3K shows a super-elastic nitinol tip that forms a funnel to reduce friction, and that the structure from a multi-lumen tube allows the use of wires to pull petals inward without damaging the tip. FIG. 3L shows the nitinol tip recoils into a straight configuration after passing over the implant.

Therefore, in some embodiments, the valve maybe fully repositioned or re-sheathed as shown in the method illustrated in FIGS. 3G-3L. In order to re-sheath the heart valve device, in some embodiments the control wires of the delivery device maybe used to deflect the petals or other anchoring members in order to re-sheath them. In one embodiment, the control wires will pass on the outside of the ventricular or atrial petals, so that so they can be used to deform inward those petals, or other anchoring elements, so that the sheath can move over them. In one embodiment, guide elements or channels on the petals or control wires may be used so as to allow mechanical deflection without the wires slipping on the surface of the petals. In some embodiments, those petals may be covered by a cloth or other surface coating which may interfere with forward sheath motion when moving forward over the petals or other anchoring elements. In such cases, the control with other elongated elements from the delivery device may be used to bend in preferential directions the cloth or other surface in order to minimize interference with the motion of the sheath. In other embodiments, other types of mechanical elements, including but not limited to wires, rods and hooks, may extend from the delivery device and allow for inward deflection of the atrial and/or ventricular petals and/or other anchoring elements in order to minimize interference with sheath in the re-sheathing process.

In some embodiments, the guide tip can have a shape or slit on its surface to interfere with the tip of the sheath. In some embodiments, the tip of the sheath has a trumpet or expanded shape, which can be collapsed and sustained in the collapsed state by mechanical interference with the guide tip. As the sheath is retracted during deployment and interference is lost with the guide tip, the distal end of the sheath expands, which allows for easier re-sheathing of the implant. An expandable sheath tip will also allow reduction of the re-sheathing force and decrease interference when the sheath moves over the petals or anchoring elements of the implant.

In some embodiments, the actuator elements can be independently controlled in order to generate desired shape changes in the inner and/or outer frame. In some embodiments, actuators on the anterior section of the external frame can be controlled independently of actuators in the posterior section of the outer frame. In this embodiment, during expansion the user may preferentially expand the anterior section of the frame to achieve the correct inter-trigonal length and expand the posterior section of the frame in order to have an improved fit and seal of the elements against the tissue.

Many modifications of the embodiments of the present disclosure will come to mind to one skilled in the art to which the disclosure pertains upon having the benefit of the teachings presented herein through the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the present invention is not to be limited to the specific embodiments disclosed and that modifications

22

and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

What is claimed is:

1. A method of implanting a prosthetic heart valve, comprising:

advancing a prosthetic heart valve to an implantation location within a patient's body, wherein the prosthetic heart valve is in a first radially contracted configuration and is releasably coupled to a delivery apparatus;

positioning the prosthetic heart valve within a native heart valve annulus;

expanding a frame of the prosthetic heart valve from the first radially contracted configuration to a first radially expanded configuration by actuating the delivery apparatus;

contracting the frame of the prosthetic heart valve from the first radially expanded configuration to a second radially contracted configuration by actuating the delivery apparatus;

repositioning the prosthetic heart valve within the native heart valve annulus while the frame of the prosthetic heart valve is in the second radially contracted configuration;

expanding the frame of the prosthetic heart valve from the second radially contracted configuration to a second radially expanded configuration by actuating the delivery apparatus; and

releasing the prosthetic heart valve from the delivery apparatus while the prosthetic heart valve is in the second radially expanded configuration, wherein releasing the prosthetic heart valve from the delivery apparatus results in radial expansion of a flange portion of the prosthetic heart valve, wherein the flange portion comprises a plurality of petals, wherein the delivery apparatus comprises a plurality of control wires disposed radially outwardly from the petals when the prosthetic heart valve is releasably coupled to the delivery apparatus, and wherein the petals expand radially outwardly beyond the control wires when the prosthetic heart valve is released from the delivery apparatus.

2. The method of claim 1, wherein contracting the frame occurs while the prosthetic heart valve is disposed outside of a sheath of the delivery apparatus.

3. The method of claim 2, wherein actuating the delivery apparatus includes moving one or more actuation wires of the delivery apparatus relative to the frame of the prosthetic heart valve.

4. The method of claim 3, wherein the frame of the prosthetic heart valve includes one or more actuation members coupled to the frame, and wherein each of the actuation wires of the delivery apparatus is coupled to a respective actuation member of the prosthetic heart valve.

5. A method of implanting a prosthetic heart valve, comprising:

advancing a prosthetic heart valve through a patient's vasculature with a delivery apparatus such that the prosthetic heart valve is disposed in or adjacent a native heart valve;

deploying the prosthetic heart valve from a sheath of the delivery apparatus;

expanding a frame of the prosthetic heart valve from a radially contracted configuration to a radially expanded configuration, wherein the prosthetic heart valve comprises one or more flanges that are retained in an at least

23

partially radially contracted configuration by control wires of the delivery apparatus;

contracting the frame of the prosthetic heart valve from the radially expanded configuration to an at least partially radially contracted configuration;

moving the prosthetic heart valve relative to the native heart valve annulus while the frame of the prosthetic heart valve is in the at least partially radially contracted configuration;

re-expanding the frame of the prosthetic heart valve from the at least partially radially contracted configuration to the radially expanded configuration;

releasing the prosthetic heart valve from the delivery apparatus by releasing the control wires from the prosthetic heart valve; and

after releasing the prosthetic heart valve from the control wires of the delivery apparatus, expanding the one or more flanges of the prosthetic heart valve from the at least partially radially contracted configuration to a radially expanded configuration.

6. The method of claim 5, wherein contracting the frame occurs while the prosthetic heart valve is radially outside and axially spaced from the sheath of the delivery apparatus.

24

7. The method of claim 5, wherein the one or more flanges of the prosthetic heart valve include an atrial flange having a plurality of atrial petals configured to engage native tissue on an atrial side of a native mitral valve.

8. The method of claim 7, wherein the control wires are disposed radially outwardly from the atrial petals while the prosthetic heart valve is coupled to the delivery apparatus, and wherein the one or more control wires are configured to radially compress the atrial petals while the prosthetic heart valve is coupled to the delivery apparatus.

9. The method of claim 5, wherein the one or more flanges of the prosthetic heart valve include a ventricular flange configured to engage native tissue on a ventricular side of a native mitral valve.

10. The method of claim 9, wherein the control wires are disposed radially outwardly from the ventricular flange while the prosthetic heart valve is coupled to the delivery apparatus, and wherein the one or more control wires are configured to radially compress the ventricular flange while the prosthetic heart valve is coupled to the delivery apparatus.

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